

REMARKS

Applicants have carefully considered this Application in connection with the Examiner's Office Action, and respectfully request reconsideration of this Application in view of the above amendments and the following remarks.

Claims 1-61 are pending in this application.

I. Claim Rejections under 35 USC §102

The Examiner has rejected Claims 1-6, 12, 13, 15-19, 21, 24, 27, 28, 30-32, 38, 39, 40-44, 46, 49, 52-54, 56, and 58-60 under 35 USC §102 as being anticipated by the Rozaklis Reference (Rozaklis et al. Clinical Chemistry, 2002). The Examiner states that Rozaklis teaches a method for diagnosing a pre-clinical status, or a clinical status of a mucopolysaccharidoses ("MPS") disease in a target patent, and goes on to states that further limitations of the claims are also anticipated.

Applicants are submitting herewith Declarations under 37 CFR 1.132 signed by Peter John Mickle, John Joseph Hopwood, Maria Fuller, Enzo Ranieri, and Steven Lewis Ramsay, stating that the inventors named in this application conceived and invented the subject matter of this application (**Exhibits 1-5**).

Applicants are submitting herewith Declarations under 37 CFR 1.132 signed by Tina Rozaklis and Phillip D. Whitfield, stating that they are not co-inventors of the subject matter of the application, and were listed as co-authors in order to receive credit for having collaborated in the research program under the inventors' direction (**Exhibits 6 and 7**).

The Rozaklis Reference is not available as a reference against the current application under 102(a), because the reference was not "described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent" (see MPEP 2132.01, 715.01(c)). Since the subject matter of the reference was derived from the same inventors as the subject matter of the current application, Applicants' disclosure of their own work within the year before the application filing date cannot be used against them under 35 U.S.C 102(a). (See MPEP 2132.01).

Applicants respectfully submit that the rejection of the claims be withdrawn.

II. Claim Rejections under 35 USC §103

A. The Examiner has rejected Claims 22, 47, and 57, under 35 USC §103 as being unpatentable over the Rozaklis Reference, stating that it would have been obvious to one of skill in the art to use an internal standard derived from a chondroitinase digestion of chondroitin sulfate having an unsaturated uronic acid at the non-reducing end in the method of the Rozaklis Reference.

As described in detail above, the Rozaklis References derived from the inventors named in the present application. Therefore, the Rozaklis Reference is not available as a reference. Applicants respectfully request that the rejection be withdrawn.

B. The Examiner has rejected Claims 7, 23, 25, 26, 33, 48, 50, and 51, under 35 USC §103 as being unpatentable over the Rozaklis Reference in view of the Byers Reference (Byers et al., *Molecular Genetics and Metabolism*, 1998).

As described in detail above, the Rozaklis References derived from the inventors named in the present application. Therefore, the Rozaklis Reference is not available as a reference.

The Examiner has based his rejection on the statement that one of skill in the art would have recognized that the GSG of the Rozaklis Reference is heparan sulfate, dermatan sulfate, keratan sulfate, or chondroitin sulfate based on the teaching of the Byers Reference. The teaching of the Byers Reference alone is only cited to draw a link between GSG and heparan sulfate, dermatan sulfate, keratan sulfate, or chondroitin sulfate.

Therefore, without the Rozaklis Reference, there can be no case for obviousness. Applicants respectfully request that the rejection be withdrawn.

C. The Examiner has rejected Claim 14 under 35 USC §103 as being unpatentable over the Rozaklis Reference in view of the Leeuwenburgh Reference (Leeuwenburgh et al., *The American*

Physiological Society, 1999), stating that it would have been obvious to one of skill in the art that the target quantity and the reference quantity are normalized to creatinine or another oligosaccharide.

As described in detail above, the Rozaklis References derived from the inventors named in the present application. Therefore, the Rozaklis Reference is not available as a reference.

The Examiner has based his rejection on the statement that that the method of the Rozaklis Reference can be modified to include normalizing of the target quantity and the reference quantity to creatine or another oligosaccharide based on the teaching of the Leeuwenburgh Reference. The Leeuwenburgh Reference is only cited to provide teaching of normalizing samples.

Therefore, without the Rozaklis Reference, there can be no case for obviousness. Applicants respectfully request that the rejection be withdrawn.

D. The Examiner has rejected Claims 20, 45, and 55, under 35 USC §103 as being unpatentable over the Rozaklis Reference in view of the Hopwood Reference (Hopwood et al., Biochemical Journal, 1985), stating that it would have been obvious to one of skill in the art to use N-acetylglucosamine-6-sulfate (“GlcNAc6S(d3)”) as an internal standard.

As described in detail above, the Rozaklis References derived from the inventors named in the present application. Therefore, the Rozaklis Reference is not available as a reference.

The Examiner has based his rejection on the statement that the method of the Rozaklis Reference can be modified to include the use of GlcNAc6S(d3) as an internal standard based on the teaching of the Hopwood Reference.

Therefore, without the Rozaklis Reference, there can be no case for obviousness. Applicants respectfully request that the rejection be withdrawn.

E. The Examiner has rejected Claims 8-11 and 34-37, under 35 USC §103 as being unpatentable over the Rozaklis Reference in view of the Byers Reference and in further view of the Merry Reference (Merry et al., The Journal of Biological Chemistry, 1999), stating that it would have been

obvious to one of skill in the art to recognize that the fragments of dermatan sulfate, heparin sulfate, keratin sulfate and chondroitin sulfate comprise combination of iduronic acid (IdoA), N-acetylgalactosamine (GalNAc), uronic acid (UA), glucuronic acid (GlcA) and sulfate (S).

As described in detail above, the Rozaklis References derived from the inventors named in the present application. Therefore, the Rozaklis Reference is not available as a reference.

The Examiner has based his rejection on the statement that the method of the Rozaklis Reference can be modified to include determining a quantity of an oligosaccharide which is a dermatan sulfate fragment using the teaching of the Byers Reference and the Merry Reference.

Therefore, without the Rozaklis Reference, there can be no case for obviousness. Applicants respectfully request that the rejection be withdrawn.

F. The Examiner has rejected Claim 61 under 35 USC §103 as being unpatentable over the Rozaklis Reference in view of the Byers Reference, the Hopwood Reference, the Leeuwenburgh Reference, and the Merry Reference, stating that the combination of the references meets all of the limitations of the current claims.

As described in detail above, the Rozaklis References derived from the inventors named in the present application. Therefore, the Rozaklis Reference is not available as a reference.

The Examiner has based his rejection on the statement that the method of the Rozaklis Reference can be modified to include a) determining a quantity of an oligosaccharide which is a dermatan sulfate; b) normalizing the result of mass spectrometry to urine level of creatine using the teaching of the Leeuwenburgh Reference; c) using GlcNAc6S(d3) as an internal standard using the teaching of the Hopwood Reference.

Therefore, without the Rozaklis Reference, there can be no case for obviousness. Applicants respectfully request that the rejection be withdrawn.

III. Conclusion

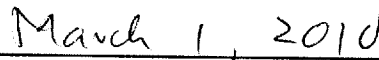
Applicants respectfully submit that, in light of the foregoing comments, all pending claims are in condition for allowance. A Notice of Allowance is therefore requested.

If the Examiner has any other matters which pertain to this Application, the Examiner is encouraged to contact the undersigned to resolve these matters by Examiner's Amendment where possible.

Respectfully submitted,



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Date

Attorney's Docket No.: MAYO-0001 (128675.00011)

Patent

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Meikle, Peter John; Fuller, Maria; Ramsey, Steve
 Lewis; Ranieri, Enzo; and Hopwood, John Joseph

Serial No.: 10/517,899

Filed: September 26, 2005 (Priority Date: June 14, 2002)

For: **IDENTIFICATION OF OLIGOSACCHARIDES AND THEIR
USE IN THE DIAGNOSIS AND EVALUATION OF
MUCPOLYSACCHARIDOSES AND OTHER RELATED
DISORDERS**

Group No.: 1797

Examiner: Xu, Xiaoyun

**DECLARATION UNDER 37 C.F.R. § 1.132 THAT INVENTORS NAMED IN THIS
APPLICATION CONCEIVED OR INVENTED THE SUBJECT MATTER OF THIS
APPLICATION WHICH IS DISCLOSED IN THE CITED PUBLICATION**

1. Cited against this application is the disclosure found in publication: Tina Rozaklis, Steven L. Ramsay, Phillip D. Whitfield, Enzo Ranieri, John J. Hopwood and Peter J. Miekle, "Determination of Oligosaccharides in Pompe Disease by Electrospray Ionization Tandem Mass Spectrometry," *Clinical Chemistry*, 48:1, 131-139, 2002.
2. We, inventors of this application and signing below, hereby declare that the cited disclosure in the above identified publication ("the Publication") was conceived or invented by us and that the inventorship of this application is correct in that the Publication discloses subject matter derived from us rather than invented by the co-authors of the Publication not named in this application, or patentee, notwithstanding the authorship of the Publication.

3. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.



Peter John Mickle

15-12-2009

Date

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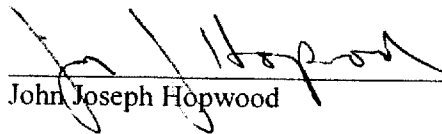
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John Joseph Hopwood

15 December 2009

Date

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Maria Fuller

15-12-09

Date

Attorney's Docket No.: MAYO-0001 (128675.00011)

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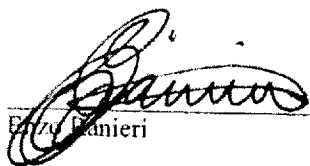
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Enzo Panieri

12/27/2010
Date

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Steven Lewis Ramsay

2009-12-15

Date

EXHIBIT 6

Attorney's Docket No.: MAYO-0001 (128675.00011)

Patent

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Meikle, Peter John; Fuller, Maria; Ramsey, Steve
Lewis; Ranieri, Enzo; and Hopwood, John Joseph

Serial No.: 10/517,899

Filed: September 26, 2005 (Priority Date: June 14, 2002)

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DISORDERS**

Group No.: 1797

Examiner: Xu, Xiaoyun

DISCLAIMING DECLARATION OF CO-AUTHOR OF PUBLICATION

I, Tina Rozaklis, residing at PROSPECT, SOUTH AUSTRALIA
declare as follows:

I. IDENTIFICATION OF INVENTION

I have read and understood the specification and claims of the invention disclosed in the U.S.
patent application ("the Invention") entitled:

Identification of Oligosaccharides and their Use in the Diagnosis and
Evaluation of Mucopolysaccherdidoses and Other Related Disorders, S/N
517,899.

the declaration of which was executed on April 14, 2005, and invented by:

Maria Fuller

Enzo Ranier
John Joseph Hopwood;

Executed on May 4, 2005, and invented by:
Peter John Meikle; and

Executed on September 21, 2005, and invented by:
Steve Lewis Ramsey

II. DETAILS OF PUBLICATION

I am listed as a co-author, along with the above-named inventor on the following publication ("the Publication"):

Tina Rozaklis, Steven L. Ramsay, Phillip D. Whitfield, Enzo Ranieri, John J. Hopwood and Peter J. Miekle, "Determination of Oligosaccharides in Pompe Disease by Electrospray Ionization Tandem Mass Spectrometry," *Clinical Chemistry*, 48:1, 131-139, 2002.

III. DISCLAIMER OF INVENTION

I confirm that, with respect to each and every oral and written disclosure set out above, I learned or received knowledge about the Invention from the above named inventors, that I am not a co-inventor of the subject matter of the above identified Invention, that I merely was involved in respect of the Invention to carry out assignments and work under the supervision and direction of the inventors, and that I was merely listed as coauthor in the Publication in order to receive credit for having collaborated in the research program under the above named inventors' direction.



Tina Rozaklis

Attorney's Docket No.: MAYO-0001 (128675.00011)

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Group No.: 1797

Examiner: Xu, Xiaoyun

DISCLAIMING DECLARATION OF CO-AUTHOR OF PUBLICATION

I, Phillip D. Whitfield, residing at 88, WARELEY CRESCENT, LIVERPOOL L9 6BW
declare as follows: UNITED KINGDOM

I. IDENTIFICATION OF INVENTION

I have read and understood the specification and claims of the invention disclosed in the U.S.
patent application ("the Invention") entitled:

Identification of Oligosaccharides and their Use in the Diagnosis and
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the declaration of which was executed on April 14, 2005, and invented by:

Maria Fuller
Enzo Ranier
John Joseph Hopwood;

Executed on May 4, 2005, and invented by:
Peter John Meikle; and

Executed on September 21, 2005, and invented by:
Steve Lewis Ramsey

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Phillip D. Whitfield 17/12/2009
Phillip D. Whitfield